

107TH CONGRESS
1ST SESSION

S. 1661

To set up a certification system for research facilities that possess dangerous biological agents and toxins, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 8, 2001

Mrs. FEINSTEIN (for herself and Mr. KYL) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To set up a certification system for research facilities that possess dangerous biological agents and toxins, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Deadly Biological
5 Agent Control Act of 2001”.

6 **SEC. 2. BIOLOGICAL WEAPONS.**

7 (a) SELECT AGENTS.—Section 175 of title 18,
8 United States Code, is amended by striking subsection (b)
9 and inserting the following:

10 “(b) SELECT AGENTS.—

1 “(1) UNCERTIFIED POSSESSION.—Whoever
2 knowingly possesses a select agent without obtaining
3 a certification from the Department of Health and
4 Human Services under section 511(f) of the
5 Antiterrorism and Effective Death Penalty Act of
6 1996, shall be fined under this title, imprisoned for
7 not more than 5 years, or both.

8 “(2) TRANSFER TO UNCERTIFIED PERSON.—
9 Any research facility that knowingly transfers a se-
10 lect agent to an entity that has not obtained a cer-
11 tification from the Department of Health and
12 Human Services under section 511(f) of the
13 Antiterrorism and Effective Death Penalty Act of
14 1996, shall be fined under this title, imprisoned for
15 not more than 5 years, or both.

16 “(c) DEFINITIONS.—In this section:

17 “(1) BIOLOGICAL AGENT; TOXIN.—The terms
18 ‘biological agent’ and ‘toxin’ have the same mean-
19 ings given those terms in section 178, except that,
20 for purposes of subsection (b), if the biological agent
21 or toxin has not been cultivated, cultured, collected,
22 or otherwise extracted from its natural source, those
23 terms do not include any biological agent or toxin
24 that is in its naturally occurring environment.

1 “(2) FOR USE AS A WEAPON.—The term ‘for
2 use as a weapon’ includes the development, produc-
3 tion, transfer, acquisition, retention, or possession of
4 any biological agent, toxin, or delivery system, other
5 than for prophylactic, protective, or other peaceful
6 purposes.

7 “(3) SELECT AGENT.—The term ‘select agent’
8 means a biological agent or toxin that—

9 “(A) is included on the list established
10 under section 511(d)(1) of the Antiterrorism
11 and Effective Death Penalty Act of 1996; and

12 “(B) is not possessed by a health, re-
13 search, or other entity listed under subpara-
14 graph (C) or (D) of section 511(f)(2) of that
15 Act.”.

16 (b) LIST OF BIOLOGICAL TOXINS.—Section 511(d)
17 of the Antiterrorism and Effective Death Penalty Act of
18 1996 (42 U.S.C. 262 note) is amended to read as follows:

19 “(d) REGULATORY CONTROL OF BIOLOGICAL
20 AGENTS.—

21 “(1) LIST OF BIOLOGICAL AGENTS AND TOX-
22 INS.—The Secretary, in consultation with the Sec-
23 retary of Defense, Attorney General, and other ap-
24 propriate Federal officials, shall—

1 “(A) annually review the existing list of se-
2 lect agents; and

3 “(B) if necessary, revise that existing list
4 of select agents.

5 “(2) CRITERIA.—In determining whether to in-
6 clude a biological agent or toxin on the list estab-
7 lished under paragraph (1), the Secretary shall—

8 “(A) consider—

9 “(i) the effect on human health of ex-
10 posure to each biological agent or toxin;

11 “(ii) the degree of contagiousness of
12 each biological agent or toxin and the
13 methods by which each biological agent or
14 toxin is transferred to humans;

15 “(iii) the availability and effectiveness
16 of vaccines and therapies to treat or pre-
17 vent any illness resulting from infection by
18 or exposure to each biological agent or
19 toxin;

20 “(iv) the potential use of each biologi-
21 cal agent or toxin in a bioterrorist attack
22 on the civilian population; and

23 “(v) any other criteria that the Sec-
24 retary considers appropriate; and

1 “(B) consult with scientific experts who
2 represent appropriate professional groups.

3 “(3) PRIORITIZATION OF COUNTER-
4 MEASURES.—The Secretary shall prioritize counter-
5 measures, including vaccines, therapies, medical de-
6 vices, and diagnostic tests which must be developed,
7 produced, or obtained in preparation for a bioter-
8 rorist attack or other significant disease emergency
9 in order to treat, prevent, or identify infection by, or
10 exposure to, biological agents and toxins, listed pur-
11 suant to this subsection.”.

12 (c) REGULATION OF POSSESSION OF BIOLOGICAL
13 AGENTS AND TOXINS.—Section 511(f) of the
14 Antiterrorism and Effective Death Penalty Act of 1996
15 (42 U.S.C. 262 note) is amended to read as follows:

16 “(f) POSSESSION AND USE OF LISTED BIOLOGICAL
17 AGENTS AND TOXINS.—

18 “(1) STANDARDS AND PROCEDURES.—The Sec-
19 retary shall provide for the establishment and en-
20 forcement of standards and procedures governing
21 the possession and use of biological agents and tox-
22 ins listed pursuant to subsection (d)(1), in order to
23 protect the health and safety of the public, including
24 safeguards to prevent access to those biological
25 agents and toxins for use in domestic or inter-

1 national terrorism, or for any other criminal pur-
2 pose.

3 “(2) CERTIFICATION.—

4 “(A) IN GENERAL.—The Secretary shall
5 establish a certification process for the posses-
6 sion and use of biological agents and toxins list-
7 ed pursuant to subsection (d)(1).

8 “(B) POSSESSION.—Except as provided in
9 subparagraph (C), the certification process es-
10 tablished under subparagraph (A) shall prohibit
11 any individual from knowingly possessing bio-
12 logical agents or toxins listed pursuant to sub-
13 section (d)(1).

14 “(C) EXCEPTION.—A health, research, or
15 other entity may possess a biological toxin or
16 agent listed pursuant to subsection (d)(1), if
17 that entity is described in subparagraph (D) or
18 (E).

19 “(D) LEGITIMATE PURPOSE.—A health,
20 research, or other entity is described in this
21 subparagraph, if—

22 “(i) the health, research, or other en-
23 tity is certified as legitimate by the De-
24 partment of Health and Human Services;

1 “(ii) the research facility has a legiti-
2 mate research or other peaceful purpose
3 for possessing the biological agent or toxin;

4 “(iii) the research facility submits to
5 periodic site inspections; and

6 “(iv) the health, research, or other en-
7 tity demonstrates the establishment and
8 enforcement of safety procedures for the
9 possession of biological agents or toxins
10 listed pursuant to subsection (d), including
11 measures to ensure—

12 “(I) proper training and appro-
13 priate skills for handling the biological
14 agents and toxins;

15 “(II) proper laboratory facilities
16 to contain and dispose of the biologi-
17 cal agents and toxins; and

18 “(III) safeguards to prevent ac-
19 cess to the biological agents and tox-
20 ins for use in domestic or inter-
21 national terrorism, or for any other
22 criminal purpose.

23 “(E) DIAGNOSTIC OR VERIFICATION PUR-
24 POSE.—A health, research, or other entity is
25 described in this subparagraph, if the entity—

1 “(i) possesses the biological agent or
 2 toxin as part of a clinical specimen in-
 3 tended for diagnostic or verification pur-
 4 poses;

5 “(ii) transfers the biological agent or
 6 toxin to another entity that is certified
 7 under this subsection, or disposes of the bi-
 8 ological agent or toxin within 72 hours in
 9 accordance with section 72.6(i) of title 42,
 10 Code of Federal Regulations; and

11 “(iii) reports the presence of the bio-
 12 logical agent or toxin to the Centers for
 13 Disease Control.

14 “(3) RESEARCH FACILITIES.—

15 “(A) IN GENERAL.—Any individual who
 16 handles biological agents or toxins in an entity
 17 certified under this subsection shall—

18 “(i) pass a criminal background
 19 check, which shall include a determination
 20 of whether that individual is a restricted
 21 person (as that term is defined in section
 22 175b of title 18, United States Code); and

23 “(ii) be registered with the Depart-
 24 ment of Health and Human Services for

1 the specific research project that requires
2 the use of biological agents or toxins.

3 “(B) PENALTIES.—

4 “(i) RESEARCH FACILITIES.—Any en-
5 tity that is certified under this subsection
6 and permits a restricted person, as that
7 term is defined in section 175b of title 18,
8 United States Code, to handle or access bi-
9 ological agents or toxins may be subject to
10 decertification by the Department of
11 Health and Human Services and civil pen-
12 alties in an amount not to exceed
13 \$500,000.

14 “(ii) SUPERVISORY PERSONNEL.—Su-
15 pervisory personnel in an entity that is cer-
16 tified under this subsection, who knowingly
17 permit a restricted person, as that term is
18 defined in section 175b of title 18, United
19 States Code, to handle or access biological
20 agents or toxins shall be subject to civil
21 penalties in an amount not to exceed
22 \$250,000 and shall be imprisoned for not
23 more than 1 year.”.

1 (d) CIVIL PENALTIES.—Section 511 of the
 2 Antiterrorism and Effective Death Penalty Act of 1996
 3 (42 U.S.C. 262 note) is amended by—

4 (1) redesignating subsection (g) as subsection
 5 (h); and

6 (2) inserting after subsection (f) the following:

7 “(g) CIVIL PENALTY.—A person who violates sub-
 8 section (e) or (f) shall be subject to the United States for
 9 a civil penalty in an amount not to exceed \$250,000 in
 10 the case of an individual and \$500,000 in the case of an
 11 entity certified under subsection (f).”.

12 (e) SECTION 511.—

13 (1) IN GENERAL.—Section 511 of the
 14 Antiterrorism and Effective Death Penalty Act of
 15 1996 (42 U.S.C 262 note) is amended—

16 (A) in subsection (e)—

17 (i) by inserting “and toxins” after
 18 “agents” each place that term appears;
 19 and

20 (ii) by inserting “or toxin” after
 21 “agent” each place that term appears; and

22 (B) in subsection (h)(1), as redesignated
 23 by this Act, by striking “the term ‘biological
 24 agent’ has” and inserting “the terms ‘biological
 25 agent’ and ‘toxin’ have”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by this subsection shall be deemed to have the same
3 effective date as section 511 of the Antiterrorism
4 and Effective Death Penalty Act of 1996 (42 U.S.C.
5 262 note).

6 (f) CONFORMING AMENDMENTS.—Section 511(e) of
7 the Antiterrorism and Effective Death Penalty Act of
8 1996 (42 U.S.C. 262 note) is amended—

9 (1) in the matter preceding paragraph (1), by
10 striking “, through regulation promulgated under
11 subsection (f),”; and

12 (2) in the heading, by striking “AGENTS” and
13 inserting “AGENTS AND TOXINS”.

14 **SEC. 3. INTERIM RULE.**

15 (a) IN GENERAL.—Not later than 30 days after the
16 date of enactment of this Act, the Secretary of Health and
17 Human Services shall promulgate an interim final rule for
18 carrying out section 511(d) of the Antiterrorism and Ef-
19 fective Death Penalty Act of 1996 (42 U.S.C. 262 note),
20 as amended by this Act.

21 (b) EFFECTIVE DATE.—The interim final rule pro-
22 mulgated under subsection (a) shall take effect 60 days
23 after the date on which the rule is promulgated, including
24 for purposes of—

1 (1) section 175(b)(1) of title 18, United States
2 Code (relating to criminal penalties), as added by
3 this Act; and

4 (2) section 511(g) of the Antiterrorism and Ef-
5 fective Death Penalty Act of 1996 (relating to civil
6 penalties), as added by this Act.

7 **SEC. 4. REGISTRATION OF BIOLOGICAL AGENTS AND TOX-**
8 **INS.**

9 In the case of a research facility that, as of the date
10 of enactment of this Act, is in possession of a biological
11 agent or toxin that is listed pursuant to section 511(d)
12 of the Antiterrorism and Effective Death Penalty Act of
13 1996, as amended by this Act, that research facility shall,
14 in accordance with the interim final rule promulgated
15 under section 3, submit an application for certification
16 under section 511(f) of the Antiterrorism and Effective
17 Death Penalty Act of 1996, not later than 30 days after
18 the date on which the rule is promulgated.

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